EXHIBIT 17

October 21, 2002

California State Board of Pharmacy
c/o Paul Riches, Legislative Analyst
400 R Street, Ste 4070
Sacramento, CA 95814

RE: California Board of Pharmacy Proposed Revisions to Title 16 CCR 1751 et seq.

Members of the California Board of Pharmacy:

The International Academy of Compounding Pharmacists ("IACP") appreciates the opportunity to comment on recent revisions to Section 1751 of Title 16 of the California Code of Regulations, entitled "Sterile Compounding Standards." IACP's mission includes increasing awareness of the importance of compounding by providing accurate information on the benefits of compounding and providing assistance to pharmacists in improving their compounding activities. In this capacity, IACP wishes to address a number of concerns related to these regulations. IACP submits these comments on behalf of its 150 California members, who will be directly impacted by these regulations, and additionally their patients, who benefit from compounded medications.

IACP initially objects to considerable inadequacies in the business impact statement presented in the formal notice of rulemaking. First, the California Board of Pharmacy grossly underestimates the fiscal impact estimates for implementation of the Sterile Compounding Standards. The rulemaking notice states, "Maximum potential cost is less than $10,000 per sterile compounding pharmacy." However, the Board provides no justification for their estimate. IACP discussions with facility and equipment suppliers have indicated that this estimate is invalid. Most sterile facility experts project realistic construction and certification costs for required Category 3 sterile compounding facilities[1] at a minimum of $20,000. In addition to facility upgrades, some compounding pharmacies would need additional equipment and devices to comply with the regulations. Thus, a *minimum* initial investment for most California pharmacies would range from $20,000 to $30,000.

Further, the discussion of financial impacts does not consider the continuing costs inherent to these regulations. Upon implementation of the Sterile Compounding Standards, pharmacies would incur several ongoing expenses. According to the regulations, pharmacists must invest much valuable time into process validation, revision of policies and procedures, and record keeping requirements. This time investment would likely require the pharmacy to hire additional staff to fulfill these administrative requirements. In addition, there are significant costs involved in the maintenance and recertification of facilities and equipment. The Board further mandates end-product testing for many compounded sterile products. Testing for sterility, potency, and endotoxin level at an independent laboratory typically adds $200-$300 cost per compounded prescription. In order to avoid financial devastation of sterile compounding operations, pharmacies must somehow increase revenues to balance the rising costs associated with complying with these regulations. However, even the California Board recognizes that increased revenues are unlikely. "The Board of Pharmacy has made an initial determination that the proposed regulations may have a significant adverse economic impact on businesses, including the ability of California businesses to compete with businesses in other states." In an increasingly competitive and global market, networking with out-of-state or international pharmacies to obtain prescription drug products at lower costs is an increasing

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[1] Facility elements include a cleanroom and anteroom (i.e. four walls, ceiling, lighting, ventilation, pass-through cabinet, etc. made of cleanroom quality material) that comply with requirements outlined in Title 16 CCR 1751.04 (b)(1).

consumer practice. Thus, in response to stringent compliance costs that will likely be distributed to consumers, California patients are likely to employ outside resources to more economically fill sterile prescriptions. Although the Board acknowledges these consumer impacts, they fail to deal with the situation they have created. In their current form, the California Sterile Compounding Standards fulfill neither objective asserted by the California Legislature in SB293. The standards would instead eliminate sterile compounding and decrease public safety as prohibitive prices encourage consumers to resource external, and potentially non-regulated, sources for prescription drugs.

In addition, to our general concerns with the rulemaking notice, IACP has several concerns with specific regulations in the Sterile Compounding Standards.

Title 16 CCR 1751.01 (d), (e), (f) "Definitions"
Title 16 CCR 1751.02 (b) "Equipment"

The California Sterile Compounding Standards repeatedly cite Federal Standard 209E, *Airborne Particulate Cleanliness Classes In Cleanrooms and Clean Zones*. However, on November 9, 2001, the U.S. General Services Administration issued a Notice of Cancellation for this standard. Federal Standard 209E has been superseded by International Organization for Standardization (ISO) Standards 14644-1 and 14644-2. This publication is available for purchase through the Institute of Environmental Sciences and Technology (IEST). However, the combined publication would cost California pharmacists $545. Due to its cancellation, access to Federal Standard 209E is already difficult and will continue to diminish. The California Board of Pharmacy should revise its definitions to cite a current, accessible, and affordable publication.

Title 16 CCR 1751.02 (j) "Records"

The California Sterile Compounding Standards require immediately retrievable patient records for each patient treated with sterile compounded medications. However, many compounding pharmacies exist outside of hospital settings and do not have access to patient charts and, thus, the data required by these standards. Obtaining information like body weight, secondary diagnosis and laboratory data is an impractical and tedious mandate for community pharmacists. The application of these requirements to all categories of sterile compounded drugs seems excessive and will more than likely aggravate the physician without improving patient care. In addition, this information does not significantly affect the compounding methods or product. The California Board likely assumes that the pharmacist would use the patient records to determine the appropriate reference category for the product being compounded. However, body weight and diagnostic information do not tell the pharmacist anything applicable to compound categorization. By definition, sterile products classified as Category 1 and Category 2 preparations have low risk of contamination. Compounding a Category 1 or Category 2 product using Category 3 procedures would not significantly increase the probability of product sterility. Category 3 compounds, on the other hand, are higher risk compounds. However, all Category 3 compounds are already subject to stringent procedural and testing requirements. Having patient diagnostic information would not raise the standard on the procedures used to compound these medications, since the highest procedural standards are already in effect. Thus, collection of this information is an impractical and tedious requirement that does not accomplish the Board's purpose. Collection and application of patient information to compounding procedures should be subject to pharmacist discretion.

Title 16 CCR 1751.03 (a) "Facility"

Statement (4) of facility requirements for Category 2 Sterile Compounds states, "In the controlled area, floors must be disinfected at least daily...." However, some pharmacies may not perform sterile compounding operations every day. This statement should be rephrased to reference the frequency of sterile compounding operations in the pharmacy.

Title 16 CCR 1751.04 (b) "Facility"

Statement (1)(A) of facility requirements for Category 3 Sterile Compounds states, "Anterooms are not required for cleanrooms equipped with pass-through cabinets that permit the movement of personnel, supplies and equipment into the cleanroom." Most pass-through cabinets are 2 ft. by 2 ft. in dimension. IACP is not aware of any pass-through cabinet that allows for movement of personnel into the cleanroom area. The California Board of Pharmacy should clarify this provision to facilitate correct application of the statute by area pharmacies.

Title 16 CCR 1751.04 (d) "Aseptic Technique & Product Preparation"

Title 16 CCR 1751.04 (d)(1) states that "products prepared from nonsterile ingredients must be tested to ensure that they do not exceed specified endotoxin limits...." Title 16 CCR 1751.04 (f)(3) states that "process validation must be supplemented with a program of end-product sterility testing, according to a formal sampling plan." The Board thus mandates endotoxin testing but requires only sampling for sterility. Lack of sterility in a product could kill a patient whereas the presence of an endotoxin would result only in a temporary fever. Thus, sterility and pyrogen testing should be of greater importance than endotoxin testing. The proposed regulation places far too much emphasis on endotoxin testing. Endotoxin testing should instead be conducted according to the pharmacist's discretion or according to a formal sampling plan.

In addition, Title 16 CCR 1751.04 (d)(1) states, "As each new lot of components and containers is received, the components must be quarantined until properly identified, tested, or verified by a pharmacist." IACP is concerned that this phrase could be interpreted to require testing of bulk drugs. Pharmacies are generally not equipped with the equipment or skill necessary to test bulk drugs for identity, potency, or sterility. In addition, the cost of this testing would be prohibitive. Pharmacists should be able to satisfy this requirement through use of their professional judgment in conjunction with a Certificate of Analysis, when applicable.

Title 16 CCR 1751.04 (d)(3)(A) mandates that all master work sheets document the "comparison of actual with anticipated yield" for Category 3 sterile compounds. For Category 2 products, however, Title 16 CCR 1751.03 (c)(1)(L) specifies that comparison of actual yield with anticipated yield must be reported when appropriate. IACP sees no justification for increasing this reporting standard. Reporting of actual versus theoretical yield is neither appropriate nor feasible in all circumstances. Pharmacists should again have the freedom to satisfy this requirement through the use of the professional discretion.

Due to the severe impact of these regulations on California pharmacies, IACP requests the California Board of Pharmacy to address the concerns outlined in these comments and issue a subsequent draft of the standards for reconsideration by pharmacies and pharmacy stakeholders. IACP appreciates the opportunity to share our concerns with the California Board of Pharmacy and we look forward to working with you on any future issues related to pharmacy compounding that we might encounter. If we can be of any assistance, or if you have any questions, please do not hesitate to contact me or Jennifer Brashares, IACP's Regulatory Affairs Coordinator, at (800) 927-4227.

Sincerely,

L.D. King
Executive Director

cc: Jennifer Brashares